R E M A R K S

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

In the outstanding Official Action, claims 26-40 were rejected under 35 USC §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time that the application was filed, had possession of the claimed invention. In light of the present amendment, it is believed that this rejection has been obviated.

Claims 26-40 have been amended so that the terms "gamma-3" and "gamma-6" have been deleted and the phrases "Ω-3" and "Ω-6" have been inserted. The terms "Ω-3" and "Ω-6" are clearly recited in the specification and found in the original claims. Thus, it is respectfully submitted that the present disclosure clearly conveys to one of ordinary skill in the art that at the time that the application was filed, Applicants had possession of the claimed invention.

Claims 26-40 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

As noted above, claims 26-40 have been amended so that the terms "gamma-3" and gamma-6" no longer appear in the claims. Moreover, claims 27-29 and 33-38 have been amended to recite the term "further" after the term "preparation". Applicants would like to thank Examiner Davis for her suggestion on this matter. Thus, it is believed to be apparent that claims 26-40 are definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 26, 30, 32, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO and BORMANN. In light of the present amendment, it is believed that this rejection has been obviated.

The present amendment is directed to a method for the prevention and/or treatment of depression. The method comprises administering orally to a person in need thereof a preparation. The preparation contains long chain polyunsaturated fatty acids, at least two different phospholipids, and at least one compound which is a factor in methionine metabolism. The present amendment recites two different phospholipids that may be selected from the group consisting of phosphatidylserine, phosphotidylinositol, phosphatidylcholine and phosphatidylethanolamine. Moreover, the present amendment incorporates the recitation that the phospholipids are in a ratio of phosphotidylcholine and/or phosphotidylethanolamine to phosphotidylserine and/or phosphotidylinositol of 0.5 - 20

(wt/wt). Support for this recitation may be found on page 8 of the present specification.

Applicants respectfully submit that the proposed combination of HORROBIN, NAITO et al., and BORMANN fail to render obvious the claimed invention. HORROBIN relates to a composition for the treatment of depression and/or anxiety. The composition may contain natural antioxidants, compositions of essential fatty acids and essential nutrients. In an effort to remedy the deficiencies of HORROBIN, the Official Action cites NAITO et al. and BORMANN.

The Official Action contends that NAITO et al. teaches phosphotidylethanolamine as a component that may be used in the treatment of depression. The Official Action further contends that BORMANN teaches that phosphotidylserine may also be used in the treatment of depression. While the Official Action concedes that the references fail to teach a method for treating depression or related disorders by administering the claimed composition, the Official Action contends that each of the claimed ingredients were well known in the art for their claimed purpose.

Applicants respectfully submit that the outstanding Official Action fails to meet its burden in showing that the claimed invention has been rendered obvious. Applicants believe that one of ordinary skill in the art would lack the motivation to combine the cited publications. Applicants respectfully

submit that it would not have been obvious to one of ordinary skill in the art that the components of the claimed compound were well known in the art for their claimed purpose. Moreover, applicants note that even if one of ordinary skill in the art were to combine and modify the teachings of the cited publications, one of ordinary skill in the art would still not obtain the claimed invention.

Applicants respectfully submit that one of ordinary skill in the art would lack the motivation to combine the cited publications. HORROBIN, NAITO et al., and BORMANN are directed to carefully formulated compositions useful in the treatment of depression or depression related disorders. However, it is noted that each of the publications take different approaches to treating depression. For example, HORROBIN relates to a composition that can be used in the treatment of depression that comprises natural antioxidants, essential fatty acids, and essential nutrients. BORMANN relates to the use of phosphotidylserine derivatives of a specific formula to treat disorders causing depression and/or disorders relating to cerebral functions. NAITO et al. relates to a polypeptide which can be used for the prevention of or in the treatment of aplasia or abnormal proliferation of glia, neurons or other cells, depression or enhancement of immunological or neurological activity, inflammatory disease, tumors or diseases induced by abnormal lipid metabolism. While NAITO et al. broadly state that

this DNA and polypeptide may be used for the diagnosis in treatment of gene diseases, it is entirely unclear whether this polypeptide and DNA would be effective for treating depression related disorders.

Applicants believe that these publications fail to provide any hint or suggestion that they may be combined with further compositions to treat depression or depression related disorders. Applicants respectfully submit that one of ordinary skill in the art would lack the motivation to combine the nutritional supplement of HORROBIN with the genetically modified polypeptide of NAITO et al. and the specifically formulated compound of BORMANN.

Applicants also respectfully submit that the outstanding Official Action fails to meet its burden in showing that each of the components of the claimed compound are well known in the art for their claimed purpose. For example, applicants respectfully submit that NAITO et al. refers to a protein that will bind phosphatidylethanolamine, but the resulting protein and not phosphatidylethanolamine itself has an action on depression (see page 6, lines 20-22). Moreover, applicants respectfully submit that while HORROBIN discloses the administration of DHA in the presence of antioxidants for treating depression, the source of DHA which is exemplified is DHA in triglyceride form. HORROBIN fails to disclose or suggest the use of at least two phospholipids. Moreover, BORMANN teaches

the use of chemically defined phosphotidylserine for treating depression. The definition of "chemically defined" is provided on page 2, line 45. The definition provides that these are not mixtures as provided in nature. Thus, applicants respectfully submit that it cannot be said that each of the components of the claimed composition were well known in the art for their claimed purpose.

Even if one of ordinary skill in the art were to combine and modify the teachings of HORROBIN, NAITO et al. and BORMANN, it is respectfully submitted that one of ordinary skill in the art would still not obtain the claimed invention. As noted above, claims 26-40 have been amended to recite that the phospholipids are in a ratio of phosphotidylcholine and/or phosphatidylethanolamine to phosphotidylserine and/or phosphatidylinositol of 0.5 - 20 (wt/wt). Applicants respectfully submit that HORROBIN, NAITO et al. and BORMANN, alone or in combination with each other fail to disclose or suggest the claimed ratio. Thus, it is respectfully submitted that the combination of HORROBIN, NAITO et al. and BORMANN fails to render obvious claims 26, 30, 32, 36 and 38.

In the outstanding Official Action, claims 26, 30-33, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO et al., BORMANN and STOLL et al. 6,344,482.

Applicants respectfully submit that STOLL et al. fail to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN. Contrary to the Official Action's contention, applicants believe that STOLL et al. does not teach "Ω-3 fatty acid, specifically phosphotidylcholine". The definition of "Ω-3-phosphotidylcholine" is given on column 3, lines 14-18. "Choline" is defined at column 3, lines 19-25 and does not encompass phosphotidylcholine. It is believed that choline bitartrate or hydroxylethyl trimethyl ammonium hydroxide are exemplified.

Moreover, applicants note that STOLL et al. fail to disclose the claimed ratio of phospholipids as set forth in claims 26-40. Thus, it is respectfully submitted that STOLL et al. fail to remedy the deficiencies of HORROBIN, NAITO et al., and BORMANN.

Claims 26, 27, 30, 32, 35, 36 and 38 were rejected under 35 USC §103(a) as being unpatentable over HORROBIN, NAITO et al., BORMANN and WO 99/66914. This rejection is respectfully traversed.

The WO 99/66914 publication relates to a composition for prevention and/or therapeutic treatment of nerve and behavioral disorders. However, the WO 99/66914 publication does not teach the claimed ratio of phosphatidylcholine and/or phosphatidylethanolamine to phosphatidylserine and/or phosphatidylinositol of from 0.5:20. Applicants respectfully

submit that the WO 99/66914 publication fails to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN.

Claims 26, 29, 30, 32, 33, 34, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO et al., BORMANN and POLLACK et al. 4,897,380. This rejection is respectfully traversed.

POLLACK et al. is directed to a composition for treating physiological disorders pertaining to the regulation neurotransmitter serotonin. However, once again, applicants respectfully submit that POLLACK et al. fail to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN. POLLACK et al. does not disclose or suggest a method for treating depression by administering to a patient in need thereof a composition comprising long chain polyunsaturated fatty acids, the phospholipids and methionine related compound as claimed. Thus, it is respectfully submitted that the outstanding Official Action fails to render obvious claims 26, 29, 30, 32, 33, 34, 36 and 38.

Claims 26, 27, 30, 32, 33, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO et al., BORMANN and DESANTIS et al. 6,096,317. This rejection is respectfully traversed.

Applicants respectfully submit that DESANTIS et al. fails to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN. DESANTIS et al. teaches a therapeutic composition and method provided for mood enhancement. The composition comprises

St. Johns Wart and a methyl donor, such as S-adenosylmethionine. Applicants respectfully submit that the limited teaching of DESANTIS et al. fails to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN.

Claims 26, 27, 30, 32 and 36-38 were rejected under 35 USC §103(a) as being allegedly being unpatentable over HORROBIN, NAITO et al, BORMANN and BEWICKE 5,820,867. This rejection is respectfully traversed.

BEWICKE relates to a novel dietary supplement composition that may be used as a general antidepressant. The dietary supplement employs an extract of St. John's Wart and additionally includes an extract of *Ginkgo biloba*, Vitamin B6, Vitamin B12, Folic acid, and Vitamin C. However, BEWICKE fails to disclose or suggest a method for the prevention and/or treatment of depression or depression related disorders as set forth in the claimed invention. BEWICKE fails to disclose or suggest the ratio of the phospholipids and fails to remedy the deficiencies of HORROBIN, NAITO et al. and BORMANN. Thus, it is respectfully submitted that claims 26, 27, 30, 32 and 36-38 are unobvious in view of HORROBIN, NAITO et al, BORMANN and BEWICKE.

In the outstanding Official Action, claims 26, 30, 32, 35, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO et al., BORMANN and OBERTHÜR et al. 6,369,042. This rejection is respectfully traversed.

OBERTHÜR et al. is directed to novel antioxidant vitamin B6 analogues. However, OBERTHÜR et al. fail to disclose or suggest a method for the prevention and/or treatment of depression as set forth in the claimed invention. OBERTHÜR et al. is completely silent as to treating disorders by the claimed method. Moreover, OBERTHÜR et al. fail to disclose or suggest the recited ratio of phospholipids found in claims 26-40. In fact, the publication relates to cosmetic compositions and does not even suggest the treatment of depression related disorders. Thus, it is respectfully submitted that the outstanding Official Action fails to meet its burden in rendering obvious claims 26, 30, 32, 35, 36 and 38.

Claims 26, 30, 32, 35, 36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, NAITO et al., BORMANN and Takeda Chem. This rejection is respectfully traversed.

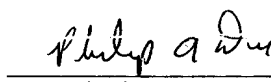
The Takeda Chem abstract discloses a depressive symptom improvement agent. The agent comprises carnitines and Vitamin B1. The composition relates to an agent designed to provide an invigorating effect to one suffering from depression related to stress and fatigue. Thus, the abstract is related to a stimulant. Moreover, the abstract fails to suggest the claimed ratio of claims 26-40, or the method as set forth by the present invention. Thus, it is respectfully submitted that the

outstanding Official Action fails to render obvious claims 26, 30, 32, 35, 36 and 38.

Attached hereto is a marked-up version of the changes made to the specification and claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

By 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 26 has been amended as follows:

--26. (amended) A method for the prevention/treatment of depression or depression related disorders, comprising administering orally to a person in need thereof a preparation which contains at least the following:

a) long chain polyunsaturated fatty acids comprising [gamma-3] Ω-3 and [gamma-6] Ω-6 fatty acids in an amount of at least 350 mg per day;

b) at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, wherein said phospholipids are in a ratio of phosphatidlylcholine and/or phosphotidylethanolamine to phosphatidylserine and/or phosphatidylinositol of 0.5 - 20 (wt/wt), and

c) at least one compound which is a factor in methionine metabolism, selected from the group consisting of folate, vitamin B12, vitamin B6, magnesium and zinc.--

Claim 27 has been amended as follows:

--27. (amended) [A] The method according to claim 26, wherein the preparation further comprises at least one of hypericin and extract of Withania somnifera.--

Claim 28 has been amended as follows:

--28. (amended) [A] The method according to claim 26, wherein the preparation further comprises citrate.--

Claim 29 has been amended as follows:

--29. (amended) [A] The method according to claim 26, wherein the preparation [contains] further comprises tryptophan or a protein containing tryptophan.--

Claim 30 has been amended as follows:

--30. (amended) [A] The method according to claim 26, wherein the [gamma-3] Ω-3 fatty acids are selected from the group consisting of eicosapentaenoic acid and docosahexaenoic acid and the [gamma-6] Ω-6 fatty acids are selected from the group consisting of arachidonic acid and dihomogammalinolenic acid.--

Claim 31 has been amended as follows:

--31. (amended) [A] The method according to claim 26, wherein b) comprises phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine.--

Claim 32 has been amended as follows:

--32. (amended) [A] The method according to claim 26, wherein c) contains at least folate and vitamin B6.--

Claim 33 has been amended as follows:

--33. (amended) [A] The method according to claim 26, wherein the preparation [contains] further comprises at least one member selected from the group consisting of SAMe, choline, betaine and copper.--

Claim 34 has been amended as follows:

--34. (amended) [A] The method according to claim 26, wherein the preparation further comprises zinc and copper, wherein the weight ratio of zinc to copper is between 5 to 12.--

Claim 35 has been amended as follows:

--35. (amended) [A] The method according to claim 26, wherein the preparation [contains] further comprises at least one member selected from the group consisting of carnitine, vitamin B1, vitamin B5 and coenzyme Q10.--

Claim 36 has been amended as follows:

--36. (amended) A method according to claim 26, wherein the preparation [contains] further comprises at least one antioxidant selected from the group consisting of vitamin C, vitamin E, lipoic acid, selenium salt and carotenoids.--

Claim 37 has been amended as follows:

--37. (amended) [A] The method according to claim 26, wherein the preparation [contains] further comprises an extract of ginkgo biloba.--

Claim 38 has been amended as follows:

--38. (amended) [A] The method according to claim 26, wherein the preparation [contains] further comprises vitamin D.--

Claim 39 has been amended as follows:

--39. (amended) [A] The method according to claim 26, wherein the preparation comprises folate, citrate, at least one of hypericin and extract of Withania somnifera, and wherein the

method comprises administering the preparation in an amount which provides a daily dose of:

at least 120 mg of long chain polyunsaturated fatty acids;

at least 200 mg phospholipids;

at least 200 µg folate;

at least one of at least 0.1 mg hypericin and at least 100 mg extract of Withania somnifera and

at least 500 mg citrate.--

Claim 40 has been amended as follows:

--40. (amended) [Method] The method according to claim 39, wherein the preparation comprises eicospentaenoic acid, docosahexaenoic acid, arachidonic acid, magnesium, zinc, vitamin B6 and vitamin B12 and wherein the method comprises administering the preparation in an amount which provides a daily dose of:

at least 20 mg eicosapentaenoic acid;

at least 50 mg docosahexaenoic acid;

at least 50 mg arachidonic acid;

at least 200 mg phospholipids;

at least 200 µg folate;

at least one of at least 0.2 mg hypericin and at least 500 mg Withania somnifera extract;

at least 100 mg magnesium;

at least 5 mg zinc;

at least 2 mg vitamin B6;

at least 2 µg vitamin B12; and

at least 1.0 g citrate.--